

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/037766

International filing date (day/month/year)
26.09.2006

Priority date (day/month/year)
26.09.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61M39/26 A61M25/00

Applicant
C. R. BARD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 17-20

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- ☒ no international search report has been established for the whole application or for said claims Nos. 17-20
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13 *ter*.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
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International application No.
PCT/US2006/037766

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-16
Industrial applicability (IA)	Yes: Claims	1-16
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery: the method step "inserting a distal end of a catheter hub into a coupling member" is usually performed during catheterization, thus it forms part of a surgical treatment of the human or animal body. Claim 20 explicitly mentions the evacuation of fluid from a patient's corpus.

Re Item V.

1 Reference is made to the following documents:

- D1 : DE 43 11 715 A1 (FRESENIUS AG [DE]) 20 October 1994 (1994-10-20)
- D2 : WO 02/04065 A2 (ICU MEDICAL INC [US]; FANGROW THOMAS F JR [US]) 17 January 2002 (2002-01-17)
- D3 : WO 03/018105 A (OCCUPATIONAL & MEDICAL INNOVAT [AU]; KIEHNE BRUCE LEIGH [AU]) 6 March 2003 (2003-03-06)
- D4 : US 2002/002351 A1 (COTE ANDREW L [US] ET AL COTE SR ANDREW L [US] ET AL) 3 January 2002 (2002-01-03)
- D5 : US 6 170 800 B1 (MELOUL RAPHAEL F [US] ET AL) 9 January 2001 (2001-01-09)
- D6 : US 2002/153503 A1 (NEWTON BRIAN L [US] ET AL NEWTON BRIAN L [US] ET AL) 24 October 2002 (2002-10-24)
- D7 : US 6 149 129 A (HARRIS CLARK EUGENE [US] ET AL) 21 November 2000 (2000-11-21)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document):

A connector system comprising a connector hub (14), a coupling member (col. 4, l. 37-38) and a deformable sealing element (46) positioned within the connector hub, the deformable sealing element configured to allow fluid flow through the connector hub upon deformation.

- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Each of documents D2-D6 also discloses the subject-matter of claim 1.

3 INDEPENDENT CLAIM 5

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 5 is not new in the sense of Article 33(2) PCT. The subject-matter of claim 5 differs from the subject-matter of claim 1 in the features the coupling member comprising "a cavity for receiving at least a portion of the catheter hub" and "an actuating member".

The actuating member is disclosed in each of document D1-D6, at least implicitly; see for example D5, ref. 420.

The cavity is also disclosed at least implicitly in the cited documents, especially in D5, showing a thread at the top end 22, 322, where a nut of the coupling member is to be fixed in order to secure the connection. The same applies for the other documents showing more or less explicitly such threads or other engagement means.

4 INDEPENDENT CLAIM 11

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is not new in the sense of Article 33(2) PCT. Document D6 discloses (the references in parentheses applying to this document):

A catheter connector system comprising: a catheter hub (10) comprising a cannula (around ref. 34) on a proximal end of the catheter hub sized for insertion into a lumen of a catheter, a distal interface (12) having a tapered seal post (24) positioned within a deformable sealing element (22) positioned further within a retention collar (18), the catheter hub further configured with a bore (52,34) for communicating a fluid from the cannula through the catheter; and a coupling member (par. [15, 16]: syringe, nozzle) comprising a cavity for receiving at least a portion of the distal interface of the catheter hub (implicitly: thread 62 needs a cavity to be received within, see ref. 64 for example of such coupling member), at least one locking member formed on an outer surface of the cavity,

the locking member having a ledge formed on an inner surface of the cavity for engaging at least a portion of the retention collar, an actuating member (par. [15, 16]: syringe, nozzle) for engaging at least a portion of the deformable sealing element, the actuating member disposed within the cavity, and a bore for communicating a fluid from the catheter hub through the coupling member (implicit feature of a syringe).

4.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 11 is furthermore known from D4 (fig. 1-6) and D5 (fig. 8).

4.3 In view of D1, D3 and D7, the subject-matter of claim 11 is regarded as lacking an inventive step over a combination of each of these documents with conventional design methods.

5 INDEPENDENT CLAIM 14

5.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 14 is not new in the sense of Article 33(2) PCT. For the reasons given above, The subject-matter of claim 14 is known from each of the cited D1-D7.

6 DEPENDENT CLAIMS 2-4, 6-10, 12, 13, 15, 16

Dependent claims 2-4, 6-10, 12, 13, 15, 16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Re Item VII.

- Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the closest prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Independent claim 1 should therefore be redrafted accordingly. If, however, the

applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of claim 1 are already known in combination from the closest prior art (see the PCT Guidelines, III-2.3a).

- The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D7 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII.

Although claims 1, 5, 11, 14 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1, 5, 11, 14 do not meet the requirements of Article 6 PCT.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).